COLOR ADDITIVE PETITION SUBMISSION

Form Approval: OMB No. XXXX-XXXX
Expiration Date: XXXXXXXXXXXX
See Reverse for OMB Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW USE OF A COLOR ADDITIVE
(Title 21, Code of Federal Regulations, 71)

FOR FDA USE ONLY

PETITION TYPE	PETITION NUMBER	RECEIVED DATE

APPLICANT INFORMATION

1. NAME OF APPLICANT

2. DATE OF SUBMISSION

3. TELEPHONE NO. *(Include Area Code)*

4. FACSIMILE (FAX) NO. *(Include Area Code)*

5. APPLICANT ADDRESS *(Number, Street, City, Country, and ZIP Code or Mail Code)*
Number and Street
Street Address

City and State
City State Code

Country

Zip Code or Mail Code
Zip_Code

6. AUTHORIZED U.S. AGENT NAME & ADDRESS *(Number, Street, City, State, ZIP code, Telephone & FAX number)* **IF APPLICABLE**
Name
Agent Name

Number and Street
Agent Address

City and State **Zip Code or Mail Code**
City ST Zip

Telephone No. (Include area code) Phone Number

Facsimile (Fax) No. (Include area code) Agent Fax Number

SUBMISSION DESCRIPTION

7. PETITION TITLE

8. ADDITIVE FUNCTION
☐ Food ☐ Drug ☐ Cosmetic ☐ Device

9. PRODUCT

10. FEE ENCLOSED
☐ Food use new listing ($3,000)
☐ Food use amendment ($1,800)
☐ Nonfood use new listing ($2,600)
☐ Nonfood use amendment ($1,600)
(Attach check made out to: U.S. Food and Drug Administration)

11. CHEMICAL IDENTITIES

CHEMICAL TYPE*	CAS NUMBER	CHEMICAL NAME	TRADE NAME (IF ANY)	STRUCTURE
P	000000000			

* P – Primary chemical, C – Constituents (including residual monomers, residual solvents, impurities, by-products, catalysts, and etc.)

APPLICATION INFORMATION

12. TYPE OF SUBMISSION (Check One)

☐ New Additive Petition ☐ Amendment* ☐ Supplement * ☐ Other

13. REASON FOR SUBMISSION

14. NUMBER OF VOLUMES SUBMITTED

15. THIS SUBMISSION IS (Check One)

☐ Paper ☐ Paper and Electronic ☐ Electronic

THIS APPLICATION CONTAINS THE FOLLOWING ITEMS: (Check all that apply)

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☐ **Cover Letter*****

☐ **Petition Table of Contents (TOC)**

☐ **Executive Summary**

21 CFR 71.1 (C)

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· **SECTION A – C: Chemistry Section**

☐ Chemistry Table of Contents (TOC)

☐ Identity ☐ Use ☐ Intended Technical Effect ☐ Analytical and Methodology

☐ Studies

☐ References

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· **SECTION D: Safety Section****

☐ Safety TOC

☐ Safety Summary

☐ Studies

☐ Genetic Toxicity Studies

☐ Acute Toxicity Studies

☐ Short Term Toxicity Studies Between 14 Days and 28 Days

☐ Subchronic Toxicity Studies 90 Days

☐ Chronic Toxicity Studies Between 6 Months and 2 Year

☐ Carcinogenicity Studies

☐ Carcinogenicity Studies with in Utero Exposure

☐ Combined Chronic Toxicity and Carcinogenicity Studies

☐ Reproductive Toxicity Studies

☐ Reproductive Toxicity with Teratology Phase

☐ Teratology Studies

☐ Immunotoxicity Studies

☐ Allergenicity Studies

☐ Metabolism and Pharmacokinetic Studies

☐ Neurotoxicity Studies

☐ Neurobehavioral Toxicity Studies

☐ Epidemiology Studies

☐ Human Clinical Studies

☐ Nutrition Studies

☐ Other Studies, e.g., Microbiology. _____

☐ References

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· **SECTION E - I: Administrative Section***

☐ Administrative TOC) ☐ Probable Exposure Information ☐ Batch Certification ☐ Exemption

☐ Required Fee (*See box 10 of page 1*) ☐ Proposed Tolerance ☐ Proposed Regulation

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· **SECTION J: Environmental Section**

☐ Environmental TOC

☐ Environmental Assessment ☐ Categorical Exclusion

☐ Studies

☐ References

21. SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	**22. TYPED NAME AND TITLE**	**23. DATE**

* The cover letter for Supplement or Amendment should be placed in Administrative folder, e.g., Administrative->Correspondences->Incoming->Supplement Cover Letter.pdf.

** All of the categories in Safety Section should be placed inside of Studies folder in Safety Folder.

*** Original Submission only.